

receptor, comprising administering [an effective amount of] a combination of an anti-ErbB2 antibody and gemcitabine [a chemotherapeutic agent other than an anthracycline derivative], in the absence of an anthracycline derivative, to the human patient in an amount effective to treat the disorder.

2. (Reiterated) The method of claim 1 wherein said disorder is a benign or malignant tumor.

3. (Reiterated) The method of claim 1 wherein said disorder is a cancer.

4. (Reiterated) The method of claim 3 wherein said cancer is selected from the group consisting of breast cancer, leukemia, squamous cell cancer, small-cell lung cancer, non-small cell lung cancer, gastrointestinal cancer, pancreatic cancer, glioblastoma, cervical cancer, ovarian cancer, liver cancer, bladder cancer, hepatoma, colon cancer, colorectal cancer, endometrial carcinoma, salivary gland carcinoma, kidney cancer, liver cancer, prostate cancer, vulval cancer, thyroid cancer, hepatic carcinoma and various types of head and neck cancer.

5. (Reiterated) The method of claim 4 wherein said cancer is breast cancer.

6. (Reiterated) The method of claim 5 wherein said cancer is metastatic breast carcinoma.

7. (Amended) The method of claim 1 wherein said antibody binds to [the] an extracellular domain of [the] ErbB2 receptor.

8. (Reiterated) The method of claim 7 wherein said antibody binds to epitope 4D5 within the ErbB2 extracellular domain sequence.

9. (Reiterated) The method of claim 8 wherein said antibody is a

humanized 4D5 anti-ErbB2 antibody.

Please cancel claims 10 and 11 without prejudice or disclaimer.

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12. (Amended) The method of claim 1 wherein the effective amount of said combination is lower than the sum of the effective amounts of said anti-ErbB2 antibody and said gemcitabine [chemotherapeutic agent], when administered individually, as single agents.

13. (Reiterated) The method of claim 1 wherein efficacy is measured by determining the time to disease progression or the response rate.

14. (Amended) An article of manufacture, comprising a container, a composition within the container comprising an anti-ErbB2 antibody, and a package insert containing instructions to avoid the use of anthracycline-type chemotherapeutics in combination with said composition and further indicating that said composition can be combined with gemcitabine.

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15. (Amended) The article of manufacture of claim 14 [further comprising a label on or associated with the container that] wherein said package insert further indicates that said composition can be used for treating a condition characterized by overexpression of ErbB2 receptor.

16. (Amended) The article of manufacture of claim 15 wherein said [label] package insert indicates that said composition can be used for the treatment of breast cancer.

17. (Amended) The article of manufacture of claim 14 wherein said anti-ErbB2 antibody binds to [the] an extracellular domain of [the] ErbB2 receptor.

18. (Reiterated) The article of manufacture of claim 17 wherein said anti-ErbB2 antibody binds to epitope 4D5 within the ErbB2 extracellular domain sequence.

19. (Reiterated) The article of manufacture of claim 18 wherein said antibody is a humanized 4D5 anti-ErbB2 antibody.

AS 20. (Amended) A method of treating ErbB2 expressing cancer in a human patient comprising administering effective amounts of an anti-ErbB2 antibody and a cardioprotectant which prevents or reduces myocardial dysfunction to the patient. B

21. (Reiterated) The method of claim 20 further comprising administering an anthracycline antibiotic to the patient.

22. (Amended) The method of claim 21 wherein the anthracycline is selected from the group consisting of doxorubicin, epirubicin, daunorubicin, carminomycin, detorubicin, esorubicin, marcellomycin, quelamycin, rodorubicin, and idarubicin.

23. (Reiterated) The method of claim 20 wherein the cancer is characterized by overexpression of ErbB2 receptor.

A6 24. (Amended) The method of claim 23 wherein the cancer is selected from the group consisting of leukemia, breast cancer, squamous cell cancer, small-cell lung cancer, non-small cell lung cancer, gastrointestinal cancer, pancreatic cancer, glioblastoma, cervical cancer, ovarian cancer, liver cancer, bladder cancer, hepatoma, colon cancer, colorectal cancer, endometrial carcinoma, salivary gland carcinoma, kidney cancer, prostate cancer, vulval cancer, thyroid cancer, hepatic carcinoma, and head [cancer] and neck cancer.

25. (Reiterated) The method of claim 20 wherein the patient has breast cancer.

26. (Reiterated) The method of claim 21 further comprising administering an additional chemotherapeutic agent to the patient.

A7 27. (Amended) The method of claim 20 wherein an anthracycline antibiotic

is not administered to the patient [with the anti-ErbB2 antibody or cardioprotectant].

28. (Reiterated) The method of claim 20 wherein the cardioprotectant is administered to the patient prior to the anti-ErbB2 antibody.

29. (Reiterated) The method of claim 20 wherein the cardioprotectant and anti-ErbB2 antibody are coadministered to the patient.

30. (Reiterated) The method of claim 20 wherein the cardioprotectant is dexrazoxane.

31. (Reiterated) The method of claim 20 wherein the cardioprotectant is probucol.

AS 32. (Amended) An article of manufacture comprising a container, a composition within the container comprising an anti-ErbB2 antibody and a package insert instructing the user of the composition to administer the anti-ErbB2 antibody composition and a cardioprotectant which prevents or reduces myocardial dysfunction to a patient.

33. (Reiterated) The article of manufacture of claim 32 comprising a second container and a cardioprotectant within the second container.

REMARKS

Amendments

Typographical errors in the specification with respect to the DiFiore and Baselga citations on pages 1 and 5, respectively, are corrected herein. In addition, the typographical errors concerning the phrase "time to disease progression" are amended on pages 15 and 46 so as to make this phrase consistent throughout the specification. The spelling of docetaxel is corrected and the TAXOTERE® trademark is identified as such on page 17.